



JG02 Rec'd PCT/PTO 03 MAY 2002  
PCT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DEX-0180

Inventors: Macina, Roberto A.

Serial No.: 09/806,302

Filing Date: 29 March 2001

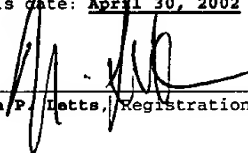
Examiner: Unknown

Group Art Unit: Unknown

Title: A Novel Method of Diagnosing,  
Monitoring, Staging, and Treating  
Gynecologic Cancers

I, Nathan P. Letts, Registration No. 36,581, certify that this correspondence is being depositing with the U.S. Postal Service as First Class mail in an envelope addressed to the Assistant Commissioner for Patents and Trademarks, Washington, D.C. 20231.

On this date: April 30, 2002

  
Nathan P. Letts, Registration No. 36,581

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the

date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- ( ) In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

- ( ) Certification in Accordance with §1.97(e) is set forth below; or

- ( ) The fee of \$180.00 as set forth in §1.17(p) is attached.

- ( ) In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(i)(1).

(XX) Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

- ( ) A copy of the of the PCT Search Report for PCT/US99/22753 which corresponds to the subject US application 09/806,302 is included.

- ( ) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were

previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. \_\_\_\_\_, filed \_\_\_\_\_, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

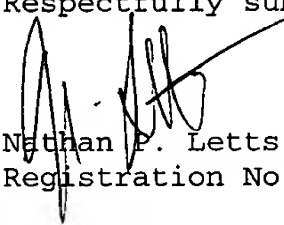
(XX) Due to the large size of some references, only relevant portions have been submitted. The included portions are as follows: WO 99/63088 A2 (pages 1-2, 23, 41, 165-167, 280-313, 331, 346-377, 439-440, 488-508, figures 177-178, ISR); WO 00/73454 A1 (pages 1-2, 23, 41, 166-168, 283-338, 356, 371-402, 465-466, 514-591, figures 177-178, ISR); WO 01/40466 A2, (pages 1-135, 212, 234-261, figures 439-440). Full text of the abbreviated reference is available if requested.

(XX) Reference WO 99/47669 A2 is in a foreign language. Therefore, a Geneseq Patent search report for the original corresponding German National Application, DE 19813839-A1, is attached to demonstrate relevance.

( ) All listed references are in the English language.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-0434. This form is submitted in duplicate.

Respectfully submitted,

  
Nathan P. Letts  
Registration No. 36,581

Date: April 30, 2002

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# SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 1

Serial Number	000002
Filing Date	29 March 2001
Applicant	Roberto A. Macina
Group Art Unit	Unknown
Examiner Name	Unknown
Attorney Docket Number	DEX-0180

## U.S. PATENT DOCUMENTS

Examiner Initials *	Cite No.	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Class	Subclass	Filing Date MM-DD-YYYY

## FOREIGN PATENT DOCUMENTS

Examiner Initials *	Cite No.	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Class	Subclass	Translation/ Comments
	AA	EP 1033401 A2	09/06/2000	Dumas Milne Edwards et al.			
	AB	WO 98/07857 A1	02/26/1998	Billing-Medel et al.			
	AC	WO 98/21331 A1	05/22/1998	Akerblom et al.			
	AD	WO 98/56248 A1	12/17/1998	Schmidt et al.			
	AE	WO 99/45147 A1	09/10/1999	Macina et al.			
	AF	WO 99/47669 A2	09/23/1999	Spect et al.			No Trans
	AG	WO 99/63088 A2	12/09/1999	Baker et al.			Abbreviated
	AH	WO 00/20043 A1	04/13/2000	Macina			
	AI	WO 00/32221 A2	06/08/2000	Ashkenazi et al.			
	AJ	WO 00/35950 A2	06/22/2000	Colpitts et al.			
	AK	WO 00/41516 A2	07/20/2000	Billing-Medel et al.			
	AL	WO 00/60076 A2	10/12/2000	Yuqiu et al.			
	AM	WO 00/73454 A1	12/07/2000	Ashkenazi et al.			Abbreviated
	AN	WO 01/40466 A2	06/07/2001	Baker et al.			Abbreviated

## OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS

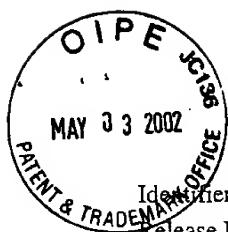
Examiner Initials *	Cite No.	Author, title of the article, title of the item, date, volume-issue number, page(s).	Translation/ Comments
	AO	Parker et al., Prostatic steroid binding protein: gene duplication and steroid binding. Nature. 01 Jul 1982; Vol. 298:92-94.	
	AP	Database EMBASE on STN, Elsevier Sci. B.V., Shina et al. Immunohistochemical analysis of estramustine binding protein with particular reference to proliferative activity in human prostatic carcinoma, abstract, Prostate, 1997, Vol. 32(1):49-58.	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



Identifier: AAZ33666 cDNA Sequence 494 BP  
Release Info: Derwent Geneseq Database Release No. 200124; Date released 26-NOV-01  
Database: WPI; 1999-528981/45.;P-PSDB; AAY48606.  
XReference:  
Accession Number: AAZ33666  
Patent Title: Human nucleic acid sequences and protein products from tumor breast tissue, useful for breast cancer therapy  
Patented by: (META-) METAGEN GES GENOMFORSCHUNG MBH.  
Inventor: Specht T, Hinzmann B, Schmitt A, Pilarsky C, Dahl E, Rosentahl A  
Description: Human breast tumour-associated EST 56.  
Patent Number: DE19813839-A1  
Patent Publication Date: 23-SEP-1999  
Modification Date: 08-DEC-1999 (first entry)  
Local Filing: 20-MAR-1998; 98DE-1013839  
Priority: 20-MAR-1998  
Abstract: This invention describes novel human nucleic acid sequences from tumor breast tissue which have cytostatic activity. They can be used to express proteins, which can be used as tools to find an activity form. They are especially useful for medicaments for gene therapy to treat breast cancer. AAZ33611-Z48617 is an invention.  
KeyWords: Expressed sequence tag;EST;human;breast;cancer;gene therapy;treatment;tumour;cytostatic;medicament;ss.  
Organism: Homo sapiens.  
Sequence Composition: Sequence 494 BP; 118 A; 127 C; 110 G; 139 T; 0 other;  
Sequence: >AAZ33666 DE19813839-A1 PA (META-) METAGEN PR 20-MAR-1998 PF 20-MAR-1998 Human breast  
CTCCCTAGGTACAAATAGCCCTGGGCTCTGCAGCTCCACAGGCTCCTGGGGTGGAGTCCA  
AATCACTCATTGTTTGTGAAAGCTGAGCTCACAGCAAAACAAGCCACCATGAAGCTGTCTG  
GTGTGTCTCCTGCTGGTCACGCTGGCCCTCTGCTGCTACCAGGCCAATGCCGAGTTCTGC  
CCAGCTCTTGTCTGAGCTGTTAGACTTCTTCTTCATTAGTGAACCTCTGTTCAAGTTA  
AGTCTTGCCAAATTTGATGCCCCCTCCGGAAGCTGTTGCAGCCAAGTTAGGAGTGAAGAGA  
TGCACGGATCAGATGTCCCTTCAGAAACGAAGCCTCATTGCGGAAGTCCTGGTGAAAATA  
TTGAAGAAATGTAGTGTGTGACATGTAAAACTTTTCATCCTGGTTTCCACTGTCTTTCAA  
TGACACCCTGATCTTCACTGCAGAAATGTAAAGGTTTCAACGTCTTGCTTTAATAAATCAC TTGCT



Identifier: AAY48606 Protein Sequence 120 AA  
Release Info: Derwent Geneseq Database Release No. 200124; Date released 26-NOV-01  
Database: WPI; 1999-528981/45.;N-PSDB; AAZ33666.  
XReference:  
Accession Number: AAY48606  
Patent Title: Human nucleic acid sequences and protein products from tumor breast tissue, useful for breast cancer therapy  
Patented by: (META-) METAGEN GES GENOMFORSCHUNG MBH.  
Inventor: Specht T, Hinzmann B, Schmitt A, Pilarsky C, Dahl E, Rosentahl A  
Description: Human breast tumour-associated protein 67.  
Patent Number: DE19813839-A1  
Patent Publication Date: 23-SEP-1999  
Modification Date: 08-DEC-1999 (first entry)  
Local Filing: 20-MAR-1998; 98DE-1013839  
Priority: 20-MAR-1998  
Abstract: This invention describes novel human nucleic acid sequences from tumor breast tissue which have cytostatic activity and isolate full-length gene sequences. They can be used to express proteins, which can be used as tools to find an or antisense form. They are especially useful for medicaments for gene therapy to treat breast cancer. AAY48606 sequence tags described in the method of the invention.  
KeyWords: Expressed sequence tag;EST;human;breast;cancer;gene therapy;treatment;tumour;cytostatic;medicament.  
Organism: Homo sapiens.  
Sequence Composition: Sequence 120 AA; 14 A; 3 R; 2 N; 3 D; 0 B; 6 C; 5 Q; 6 E; 0 Z; 2 G; 2 H; 3 I; 23 L; 11 K; 2 M; 7 F; 6 P; 9 S;  
Sequence: >AAY48606 DE19813839-A1 PA (META-) METAGEN.PR 20-MAR-1998 PF 20-MAR-1998 Human breast  
PWALQLHRLLGWSPNHSFLFVKAELTAKQATMKLSVCLLLVTLALCCYQANAEEFCPALVSE  
LLDFFFISEPLFKLSLAKFDAPPEAVAAGLVKRCCTDQMSLQKRSLIAEVLVKILKKCSV